SECTION 2 – 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 8807.92

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JAN 2 3 2003

Device Name
Trade Name: Rapid Thermal Exchange System
Common Name: System, Thermal Regulating
Classification Name: Thermal Regulation System Accessory (21 CFR 870.5900)

Predicate Devices
Palmo Thermoregulating Accessory K014210

Device Description
The Rapid Thermal Exchange (RTX) System consists of three main parts. The 1) Field Controller unit is the vacuum source; it also regulates and pumps the temperature-controlled water through the 2) Attachment Hoses that are connected to 3) the Thermal Exchange Chamber (identified in earlier submissions as the Palmo Thermoregulating Accessory).

The patient inserts his/her hand through the arm seal of the Thermal Exchange Chamber. The palm is placed on the temperature-controlled thermal exchange surface. A light vacuum is created by connecting the Thermal Exchange Chamber to the Field Controller Unit's vacuum pump via the inline vacuum control valve. The physician can monitor the adequacy of the vacuum and seal from the dial on the mechanical vacuum gauge mounted to the top of the Thermal Exchange Chamber. A light vacuum (25 inches of water, 47mmHg) is applied to increase the amount of blood available in the appendage.

This combination of light vacuum and a thermal exchange surface provides a rapid and noninvasive mechanism for changing the temperature of the blood flowing through the appendage. This, in turn, changes the temperature of the body core.

The arm seal of the Thermal Exchange Chamber is available in three different sizes (small, medium & large) to accommodate the range of possible hand and wrist sizes of athletes. A variation of the Chamber can be applied to the foot in a similar manner.

Indications for Use

The Rapid Thermal Exchange System is designed to noninvasively lower or raise a patient's temperature and/or maintain a desired patient temperature. This is accomplished with local application of negative pressure and heating/cooling to a distal appendage.

Testing in Support of Substantial Equivalence Determination

The thermal exchange chamber (aka the Palmo) is unchanged since the predicate submission. The operating characteristics are also unchanged.

The results of bench testing support the claims that the RTX System can maintain the desired operating characteristics. In addition, the manufacturer claims that the RTX system has been designed, tested and manufactured in compliance with the FDA consensus standard IEC 60601-1 (*Medical Electrical Equipment – Part 1: General requirements for safety*).

Additionally, human studies reported in a predicate submission have demonstrated that the simultaneous application of light vacuum and thermal exchange can effectively and noninvasively change the body core temperature of a patient.

Substantial Equivalence Conclusion

Substantial equivalence is based on the fact that the RTX System has the same intended use as the Palmo Thermoregulating Accessory (K014210).

The RTX System uses the same technique and operating parameters as the Palmo Thermoregulating Accessory (Palmo). The Palmo consisted of a vacuum chamber for the distal appendage that served as the thermal exchange surface, an arm seal, an in-line vacuum relief valve and Attachment hoses. The RTX System uses the exact same components.

The Palmo Thermoregulating Accessory was cleared as an accessory to the Cincinnati SubZero Blanketrol II. The Blanketrol II pumped its temperature-controlled water through the Palmo thermal exchange chamber. The RTX System has a water heater/cooler in its Field Controller Unit (FCU) that pumps temperature-controlled water through the same Palmo thermal exchange chamber. The Palmo Thermoregulating Accessory was cleared to use a hospital's central vacuum as a vacuum source for the Palmo thermal exchange chamber. The FCU has its own vacuum pumps as a vacuum source for the same Palmo thermal exchange chamber. Since the RTX provides both temperature-controlled water and vacuum sources in a suitcase-sized, wheeled, Field Control Unit, it can be applied in a wider range of locations.

The RTX System requires the prescription or order of a physician to be applied in response to medical conditions.

The Palmo and the RTX System use identical technology, methods and temperature/vacuum settings to exchange thermal energy with the body core of the patient. The technology uses a local application of negative pressure and a thermal exchange surface to a distal appendage. There are no new questions of safety or efficacy raised between the two systems.

AVAcore Technologies certifies that the RTX System is in compliance with the following FDA recognized consensus standard: IEC 60601-1: *Medical Electrical Equipment – Part 1: General requirements for safety.*

The predicate device is classified as a "Thermal Regulating System" (per 21CFR870.5900), as is the RTX. Therefore, it can be concluded that the RTX System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2003

AVACore Technologies, Inc.
c/o Mr. Michael Kwan
Underwriters Laboratories Inc.
1655 Scott Boulevard
Santa Clara, CA 95050

Re: K023934
Trade Name: Rapid Thermal Exchange (RTX) System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulation System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: January 13, 2002
Received: January 14, 2003

Dear Mr. Kwan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Rapid Thermal Exchange (RTX) System

Indications for Use

The Rapid Thermal Exchange System is designed to noninvasively lower or raise a patient's temperature and/or maintain a desired patient temperature. This is accomplished with local application of negative pressure and heating/cooling to a distal appendage.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023934